

05-21-04

IFW

DOCKET NO. HARR0032-101

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Lawrence S. Young et al. Confirmation No.: 5440

Serial No.: 10/607,479

Art Unit: 1645

Filing Date: June 26, 2003

Examiner: Not Yet Assigned

For: GENE EXPRESSION USING T CELL FACTOR RESPONSIVE ELEMENT

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DATE OF DEPOSIT: May 20, 2004

MAIL STOP AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed. The Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

This Information Disclosure Statement is being filed:

- ☐ within three months of the filing date of the patent application.
- ☐ within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.
- ☒ **before** the mailing date of a first Office Action on the merits.
- ☐ **after** the mailing date of a first Office Action on the merits, but before the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, and accordingly is accompanied by:
 - ☐ the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below);

or

- ☐ the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or
- ☒ No fee is owed by the applicant(s).
- ☐ In accordance with 37 C.F.R. § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below) and the fee of \$180.00 as set forth in 37 C.F.R. § 1.17(p), is attached.
- ☐ **after** the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, but before, or simultaneously with, the payment of the Issue Fee, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e), a Petition requesting consideration of the Information Disclosure Statement and the Petition Fee of \$130.00 set forth in 37 C.F.R. § 1.17(i)(1) (see "Statement," "Petition," and "Fees" below).
- ☒ Copies of references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are enclosed herewith

EXCEPT THAT:

- ☐ In view of the voluminous nature of references _____, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with 37 C.F.R. § 1.98(d), copies of the following references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application.
- ☒ Copies of references **AA-BX** listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 were previously cited by or submitted to the U.S. Patent and Trademark Office in **Application Serial No. 09/798,128, Filed March 2, 2001, now U.S. Patent No. 6,608,037, Issued August 19, 2003.**
- ☒ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

Statement

- ☐ The undersigned attorney hereby states that each item information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.

Petition

- ☐ Applicant(s) hereby petitions the Assistant Commissioner to consider the references listed in this Information Disclosure Statement, on the enclosed Form PTO 1449, and the examination of the above-identified patent application.

Fees

- ☒ No Fee is owed by the applicant(s).
- ☐ The Information Disclosure Statement Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.
- ☐ The Petition Fee of \$130.00 under 37 C.F.R. § 1.17(i)(1) is enclosed herewith.

Method of Payment of Fees

- ☐ Attached is a check in the amount of \$_____. This form is submitted in duplicate.
- ☐ Charge Deposit Account No. 50-1275 in the amount of \$_____. This form is submitted in duplicate.
- ☐ Please charge any deficiency or credit any overpayment to Deposit Account 50-1275.
- ☒ No fee or Statement is required under 37 C.F.R. § 1.97(b).

There are no listed references, which are not in the English language.

Respectfully submitted,



Doreen Yatko Trujillo
Registration No. 35,719

Dated: May 20, 2004

COZEN O'CONNOR, P.C.
1900 Market Street, 6th Floor
Philadelphia, PA 19103-3508
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Substitute for form 1449A/PTO

(Use as many sheets as necessary)

Sheet

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of

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Complete if Known

Application Number

10/607.479

Filing Date

June 26, 2003

First Named Inventor

Lawrence S. Young et al.

Art Unit

1645

Examiner Name

Not Yet Assigned

Attorney Docket Number

HARR0032-101

U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

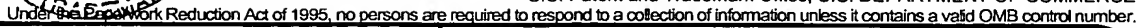
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
|--------------------|-----------------------|---|--------------------------------|---|---|----------------|
| | | Country Code ³ - Number ⁴ - Kind Code ⁵ (if known) | | | | |
| | AB | EP 0 939 122 A1 | 09/01/1999 | Universiteit Utrecht | | Yes |
| | AC | WO 91/17773 | 11/28/1991 | Birnstiel et al. | | Yes |
| | AD | WO 91/18088 | 11/28/1991 | Chatterjee and Wong | | Yes |
| | AE | WO 93/08288 | 04/29/1993 | Anlezark et al. | | Yes |
| | AF | WO 93/18759 | 09/30/1993 | Smith and Woo | | Yes |
| | AG | WO 95/02698 | 01/26/1995 | Jessee | | Yes |
| | AH | WO 95/30020 | 11/09/1995 | Midoux et al. | | Yes |
| | AI | WO 96/41606 | 12/27/1996 | Thatcher et al. | | Yes |
| | AJ | WO 98/07876 | 02/26/1998 | Antoniou and Grosveld | | Yes |

| | | | |
|-----------------------|--|--------------------|--|
| Examiner Signature | | Date Considered | |
|-----------------------|--|--------------------|--|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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|-------------------------------|---------------------------------|
| <i>Application Number</i> | 10/607,479 |
| <i>Filing Date</i> | June 26, 2003 |
| <i>First Named Inventor</i> | Lawrence S. Young et al. |
| <i>Art Unit</i> | 1645 |
| <i>Examiner Name</i> | Not Yet Assigned |
| <i>Attorney Docket Number</i> | HARR0032-101 |

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| Sheet | 2 | of | 5 |
|-------|---|----|---|

[illegible][illegible]Date
Considered

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 3 of 5

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| | |
|------------------------|--------------------------|
| Application Number | 10/607,479 |
| Filing Date | June 26, 2003 |
| First Named Inventor | Lawrence S. Young et al. |
| Art Unit | 1645 |
| Examiner Name | Not Yet Assigned |
| Attorney Docket Number | HARR0032-101 |

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|------------------------|--------------------------|---|----------------|
| | AN | Anderson, W.F., "Human gene therapy," <i>Nature</i> , 392 (Supp):25-30, April 30, 1998 | |
| | AO | Calos, M., "The potential of extrachromosomal replicating vectors for gene therapy," <i>TIG</i> , 12(11):463-466, 1996 | |
| | AP | Chowdhury, J.R. et al., "Long-Term Improvement of Hypercholesterolemia After ex Vivo Gene Therapy in LDLR-Deficient Rabbits," <i>Science</i> , 254:1802-1805, December 20, 1991 | |
| | AQ | Cotton, M. et al., "Receptor-Mediated Transport of DNA into Eukaryotic Cells," <i>Meth. Enzymol.</i> , 217:618-644, 1992 | |
| | AR | Eastman, Q. and Grosschedl, R., "Regulation of LEF-1/TCF transcription factors by Wnt and other signals," <i>Current Opin. Cell Biol.</i> , 11:233-240, 1999 | |
| | AS | Emerson, S.G., "Ex Vivo Expansion of Hematopoietic Precursors, Progenitors, and Stem Cells: The Next Generation of Cellular Therapeutics," <i>Blood</i> , 87(8):3082-3088, April 15, 1996 | |
| | AT | Fallaux, F.J. et al., "New Helper Cells and Matched Early Region 1-Deleted Adenovirus Vectors Prevent Generation of Replication-Competent Adenoviruses," <i>Human Gene Ther.</i> , 9:1909-1917, September 1, 1998 | |
| | AU | Flotte, T.R. et al., "Stable in vivo expression of the cystic fibrosis transmembrane conductance regulator with an adeno-associated virus vector," <i>Proc. Natl. Acad. Sci. USA</i> , 90:10613-10617, November, 1993 | |
| | AV | He, T.C. et al., "Identification of c-MYC as a Target of the APC Pathway," <i>Science</i> , 281:1509-1512, September 4, 1998 | |
| | AW | Hengge, U.R. et al., "Cytokine gene expression in epidermis with biological effects following injection of naked DNA," <i>Nature Genetics</i> , 10:161-166, 1995 | |
| | AX | Hickman, M.A. et al., "Gene Expression Following Direction Injection of DNA into Liver," <i>Human Gene Ther.</i> , 5:1477-1483, December, 1994 | |
| | AY | Hitt, M.M. et al., "Human Adenovirus Vectors for Gene Transfer into Mammalian Cells," <i>Advances in Pharmacology</i> , 40:137-206, 1997 | |
| | AZ | Keown, W.A. et al., "Methods for Introducing DNA into Mammalian Cells," <i>Methods Enzymol.</i> , 185:527-537, 1990 | |

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|-----------------------|--|--------------------|--|
| Examiner Signature | | Date Considered | |
|-----------------------|--|--------------------|--|

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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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|---|------------------------|--------------------------|--------------------------|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | Complete if Known | |
| | | Application Number | 10/607,479 |
| | | Filing Date | June 26, 2003 |
| | | First Named Inventor | Lawrence S. Young et al. |
| | | Art Unit | 1645 |
| | | Examiner Name | Not Yet Assigned |
| Sheet 4 of 5 | Attorney Docket Number | HARR0032-101 | |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|--|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| | BA | Korinek, V. et al., "Constitutive Transcriptional Activation by a β -catenin-Tcf Complex in APC ⁺ Colon Carcinoma," <i>Science</i> , 275:1784-1787, March 21, 1997 | |
| | BB | Kucherlapati, R. and Skoultschi, A.I., "Introduction of Purified Genes into Mammalian Cells," <i>Crit. Rev. Biochem.</i> , 16(4):349-379, 1984 | |
| | BC | Lickert, H. et al., "Wnt/ β -catenin signaling regulates the expression of the homeobox gene <i>Cdx1</i> in embryonic intestine," <i>Development</i> , 127:3805-3813, 2000 | |
| | BD | Love, J.J. et al., "Structural basis for DNA bending by the architectural transcription factor LEF-1," <i>Nature</i> , 376:791-795, August 31, 1995 | |
| | BE | Mack, K.D. et al., "Cationic Lipid Enhances In Vitro Receptor-Mediated Transfection," <i>The American Journal of the Medical Sciences</i> , 307(2):138-143, 1994 | |
| | BF | Meyer, K.B. et al., "Intratracheal gene delivery to the mouse airway: characterization of plasmid DNA expression and pharmacokinetics," <i>Gene Therapy</i> , 2:450-460, 1995 | |
| | BG | Morin, P.J. et al., "Activation of β -Catenin-Tcf Signaling in Colon Cancer by Mutations in β -Catenin or APC," <i>Science</i> , 275:1787-1790, March 21, 1997 | |
| | BH | Miller, J.L. et al., "Recombinant adeno-associated virus (rAAV)-mediated expression of a human γ -globin gene in human progenitor-derived erythroid cells," <i>Proc. Natl. Acad. Sci. USA</i> , 91:10183-10187, October, 1994 | |
| | BI | Philip, R. et al., "Efficient and Sustained Gene Expression in Primary T Lymphocytes and Primary and Cultured Tumor Cells Mediated by Adeno-Associated Virus Plasmid DNA Complexed to Cationic Liposomes," <i>Mol. Cell. Biol.</i> , 14(4):2411-2418, April 1994 | |
| | BJ | Plank, C. et al., "The Influenced of Endosome-disruptive Peptides on Gene Transfer Using Synthetic Virus-like Gene Transfer Systems," <i>J. Biol. Chem.</i> , 269(17):12918-12924, April 29, 1994 | |
| | BK | Russell, D.W. et al., "Adeno-associated virus vectors preferentially transduced cells in S phase," <i>Proc. Natl. Acad. Sci. USA</i> , 91:8915-8919, September, 1994 | |
| | BL | Shtutman, M. et al., "The cyclin D1 gene is a target of the β -catenin/LEF-1 pathway," <i>Proc. Natl. Acad. Sci. USA</i> , 96:5522-5527, May, 1999 | |
| | BM | Sikes, M.L. et al., "In Vivo Transfer into Rabbit Thyroid Follicular Cells by Direct DNA Injection," <i>Human Gene Ther.</i> , 5:837-844, 1994 | |

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|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 5 of 5

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| Application Number | 10/607,479 |
| Filing Date | June 26, 2003 |
| First Named Inventor | Lawrence S. Young et al. |
| Art Unit | 1645 |
| Examiner Name | Not Yet Assigned |
| Attorney Docket Number | HARR0032-101 |

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|---------------------|-----------------------|---|----------------|
| | BN | Tetsu, O. and McCormick, F., "β-Catenin regulates expression of cyclin D1 in colon carcinoma cells," <i>Nature</i> , 398:422-426, April 1, 1999 | |
| | BO | Trubetskoy, V.S. et al., "Use of N-Terminal Modified Poly(L-lysine)-Antibody Conjugate as a Carrier for Targeted Gene Delivery in Mouse Lung Endothelial Cells," <i>Bioconjugate Chem.</i> , 3:323-327, 1992 | |
| | BP | Ustav, M. and Stenlund, A., "Transient replication of BPV-1 requires two viral polypeptides encoded by the E1 and E2 open reading frames," <i>The EMBO J.</i> , 10(2):449-457, 1991 | |
| | BQ | van de Wetering, M. et al., "Identification and cloning of TCF-1, a T lymphocyte-specific transcription factor containing a sequence-specific HMG box," <i>The EMBO J.</i> , 10(1):123-132, 1991 | |
| | BR | Vile, R.G. and Hart, I.R., "In Vitro and in Vivo Targeting of Gene Expression to Melanoma Cells," <i>Cancer Res.</i> , 53:962-967, 1993 | |
| | BS | Walsh, C.E. et al., "Regulated high level expression of a human γ-globin gene introduced into erythroid cells by an adeno-associated virus vector," <i>Proc. Natl. Acad. Sci. USA</i> , 89:7257-7261, August, 1992 | |
| | BT | Watanabe, M. et al., "Nucleotide sequence of <i>Salmonella typhimurium</i> nitroreductase gene," <i>Nucleic Acids Res.</i> , 18(4):1059, 1990 | |
| | BU | Wilson, J.M. et al., "Ex Vivo Gene Therapy of Familial Hypercholesterolemia," <i>Human Gene Ther.</i> , 3:179-222, 1992 | |
| | BV | Wilson, J.M. et al., "Hepatocyte-directed Gene Transfer in vivo Leads to Transient Improvement of Hypercholesterolemia in Low Density Lipoprotein Receptor-deficient Rabbits," <i>J. Biol. Chem.</i> , 267(2):963-967, January 15, 1992 | |
| | BW | Wolff, J.A. et al., "Direct Gene Transfer into Mouse Muscle in Vivo," <i>Science</i> , 247:1465-1468, March 23, 1990 | |
| | BX | Wu and Wu, "Receptor-mediated Gene Delivery and Expression in Vivo," <i>J. Biol. Chem.</i> , 263(29):14621-14624, October 15, 1988 | |
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| Examiner Signature | | Date Considered | |
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